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December 12, 2005

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket number 2005D-0330 (Guidance for Industry and FDA Review Staff; Collection of Platelets by Automated Methods

Greetings:

This correspondence serves to convey comments from the professional staff of Lane Memorial Blood Bank to the Food and Drug Administration regarding draft guidance for automated collection of blood components. We appreciate the opportunity to submit observations regarding the proposed guidance. Our comments are as follows:

1. **Section II. A.**
   "Because of the continuing problem of bacterial contamination of blood components and associated transfusion risks, we continue to believe that bacterial contamination testing is a necessary part of process validation and quality assurance monitoring."

   Screening by culture has been an integral part of quality control testing for apheresis platelets in our establishment since March of 2004. Because of the frequent reference made by the FDA to testing for bacterial contamination, we believe it would be helpful for the agency to establish the requirements in the regulations and license products accordingly.

2. **Section III. A.**
   "Prior to the first donation, test Platelets, Pheresis donors for levels of the following laboratory values that are acceptable under the manufacturer's directions for use: . . . WBC count . . ."

   We are unsure of the clinical value of assaying the donor's white blood cell count prior to platelet donation and recommend removal of this requirement.

3. **Section III. A.**
   "You should not collect Platelets, Pheresis from donors who have ingested drugs that adversely affect platelet function. These include, but may not be limited to:
   - *Aspirin (ASA)/ASA-containing drugs – 5 days from last dose*
   - *Non-steroidal Anti-inflammatory Drugs (NSAIDS) – 3 days from last dose*
   - *Plavix (Clopidogrel) – 5 days from last dose . . ."*

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We believe the following deferral periods adequately serve to prevent collection of platelets with reduced hemostatic function:

- Aspirin: 48 hours
- NSAIDs: 24 hours
- Plavix: 48 hours

4. **Section III. B. 2.**
"To protect the safety of the donor: . . .
    - *You should collect no more than 24 total Platelets, Pheresis components in a 12-month period. Two components collected from a double collection of Platelets, Pheresis and three components collected from a triple collection of Platelets, Pheresis would be counted as two components and three components respectively.*
    - *A post-donation platelet count should be performed after each collection."*

We believe the safety of double and triple platelet collections has been well-established over the past decade and the adequacy of platelet inventory rests on this multiple-component collection efficiency. In our center where the rate of split component production is moderate, our existing donor base would require an increase of 32% to support transfusion needs of our client hospitals. Many other centers would be more severely affected by implementation of this change. Because of the challenge in recruiting apheresis platelet donors, we recommend return of this requirement to no more than 24 donation episodes per year without the stipulation that each component collection counts toward the total.

We also believe that the safety of platelet donation has been well-established in general, making this proposed requirement for a post-collection platelet count unnecessary. We perform a pre-donation platelet count to establish both the platelet donors' suitability to donate and to indicate that the donor's platelet count will be sufficient to ensure post-donation hemostasis.

5. **Section III. B. 3.**
"To protect the donor from significant RBC loss, we recommend that: . . .
    - *A donor who donated a single unit of Red Blood Cells by apheresis may serve as a Platelets, Pheresis donor within 8 weeks if the extracorporeal red blood cell volume during the current procedure is expected to be less than 100 mL.*
    - *You not allow a donor who has donated a single unit of Red Blood Cells plus platelets or plasma in the previous 8 weeks to donate Platelets, Pheresis, unless the extracorporeal volume during the current procedure is expected to be less than 100 mL.*

We question the inconsistency of extracorporeal volume in these paragraphs, and would like clarification if both should refer to extracorporeal red blood cell volume.

6. **Section III. B. 4.**
"Total volume loss per collection procedure: The total volume (excluding anticoagulant of all blood components retained per collection of Platelets, Pheresis should not exceed 500 mL (600 mL for donors weighing 175 lbs or greater) or the volume described in the labeling for the device, whichever is less."

We employ the Baxter Amicus® collection system, which has been approved by the FDA for collection of 600 mL if a donor weighs less than 175 lbs, and 700 mL if a donor weighs more than 175 pounds. We recommend that the agency continue to allow volumes collected to be consistent with approved operating instructions.

7. **Section III. B. 5.**

"We believe a physician should be present on the premises during the collection of Platelets, Pheresis to ensure that necessary medical treatment be available to the donor in a timely fashion. We interpret 'present on the premises' to include a qualified physician able to arrive at the premises within 15 minutes. In case of an emergency, calling 911 may be used to obtain emergency medical care and transportation to another facility for further care, but we do not believe this is a sufficient substitute for an available physician as previously described."

We believe the imposition of this requirement ignores the relative safety record established by blood centers performing automated platelet collections both in fixed sites and in mobile settings, and believe further that the imposition of this standard would increase expense of operation without increasing donor safety. Because we have no record of serious donor reaction requiring direct and immediate physician intervention, we believe it is sufficient to employ a qualified medical director to establish local requirements and qualified collection staff able to provide adequate nursing care.

8. **Section IV.**
"A statement that the long-term effects of repeated plateletpheresis on the donor's platelet and leukocyte count is not understood."

We acknowledge that controlled studies of the long-term effects of repeated plateletpheresis have not been performed; however, we believe this statement is unnecessary in light of the apheresis safety record accumulated by the industry.

9. **Section VI. B.**
"Minimum/maximum acceptable values for the Platelets, Pheresis collection and/or component as specified by the device manufacturer . . .
    - *Residual WBC count for the collection (if leukocyte reduced) and percent recovery."*

We believe a determination of percent recovery of platelets is applicable only to leukoreduction systems employing filters. Guidance should clarify that percent recovery is not applicable to collection systems capable of producing a leukoreduced platelet concentrate without filtration.

10. **Section VI. D.**
"Perform bacterial contamination testing on 500 collections with 0 failures."

This requirement is burdensome to smaller blood centers such as ours, where fewer than 1000 apheresis platelets are collected annually; this recommendation for performance qualification would require over 5 months to complete in our center. We recommend allowing centers to establish a statistically significant sample appropriate to the activity level of the blood center.

11. **Section VII. A. 2.**
"Additional Provisions Applicable to SOPS
    - ***Actual platelet yield:*** *The platelet yield from each collection of Platelets, Pheresis should be provided to the transfusion facility.*
    - ***Total volume loss:*** *Annual volume loss should not exceed 12 liters (12,000 mL) per year for donors weighing 110 – 175 lbs; 14.4 liters (14,400 mL) per year for donors weighing more than 175 lbs).*

We believe it is essential to meet requirements for a potent product to achieve therapeutic effectiveness. We consider this adequate and preferable to implementing an additional labeling requirement. We believe it is reasonable simply to provide this information to our hospital

transfusion services upon request. In addition, the requirements in this section do not seem to be entirely consistent with the labeling requirements in section IX.

We employ the Baxter Amicus® collection system, which has been approved by the FDA for total annual volume loss of 14,400 mL for donors weighing 110 - 175 lbs and 16,800 for those weighing over 175 lbs. We recommend that the agency continue to allow volumes collected to be consistent with approved operating instructions.

12. **Section VII. B.**
"In addition, you should monitor donors undergoing frequent multiple component collection of Platelets, Pheresis for platelet recovery."

We would like to request clarification of this statement. It is unclear what the agency intends to establish as requirements for monitoring donors for platelet recovery.

Thank you for the opportunity to comment on this noteworthy document. We look forward to the publication of final guidance that reflects the significant investment of both the agency and the industry, and one that is representative of our collaborative efforts.

Sincerely,

DOUGLAS A. ENGEL
Authorized Official